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President's Budget Blueprint Seeks Changes for Public Health Service Agencies

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Related Author

• C. Stephen Redhead

C. Stephen Redhead, Specialist in Health Policy (credhead@crs.loc.gov, 7-2261)

The White House has released a "budget blueprint" that outlines President Trump's priorities for funding the federal government in FY2018. The document covers only discretionary spending, which is controlled through the annual appropriations process. It does not address mandatory spending—including spending on entitlement programs such as Medicare and Social Security—or interest payments on the federal debt. The complete FY2018 budget is expected to be released in May.

Although the budget blueprint provides limited details on the agency, account, or program level, it indicates Trump Administration support for billions of dollars in cuts to government agencies to counterbalance increases in military and national security spending. The blueprint includes several recommendations that would make significant changes to the budget and operations of the <u>Public Health Service (PHS) agencies</u> within the Department of Health and Human Services.

Research

The budget blueprint proposes reducing <u>National Institutes of Health (NIH)</u> funding for biomedical and behavioral research by \$5.8 billion from the annualized FY2017 level to \$25.9 billion. While no other details are provided, this would appear to return NIH's funding in real (i.e., inflation-adjusted) terms to the levels of the late 1990s. The blueprint also calls for a "major reorganization of NIH's Institutes and Centers to help focus resources on the highest priority research" and "other consolidation and structural changes."

The NIH proposal contrasts with recent legislative actions to increase NIH's budget after several years of gradually declining funding. Lawmakers increased NIH's annual appropriation for FY2016 by \$2 billion over the FY2015 level. In addition, the newly enacted 21st Century Cures Act established the NIH Innovation Account and authorized annual transfers to the fund over a 10-year period totaling \$4.8 billion. Each year, funds in the Innovation Account are available to be appropriated to help support the Precision Medicine Initiative, the BRAIN initiative, cancer research, and the use of adult stem cells in regenerative medicine. The blueprint does not mention these or other specific research areas.

The blueprint also proposes consolidating the Agency for Healthcare Research and Quality (AHRQ) within NIH.

AHRQ funds—and disseminates the findings of—research to improve the safety, quality, and affordability of health care. Its budget is about 1% of NIH's budget. Appropriators have recommended eliminating funding for AHRQ, saying that the agency's work overlaps with research supported by NIH and the <u>Patient-Centered Outcomes Research Trust</u> Fund (PCORTF). Supporters of AHRQ argue that the agency has a distinct mission and that its research portfolio focuses on different questions.

AHRQ's discretionary funding has declined in recent years, though this has been offset by the annual transfer of PCORTF funds to the agency. Each year, AHRQ receives a portion of the PCORTF funding, which it uses to disseminate and implement the findings of comparative clinical effectiveness research funded by the PCORTF.

Public Health

The budget blueprint proposes a new fund—the Federal Emergency Response Fund—to help the government respond rapidly to disease outbreaks such as Zika and Ebola. Public health officials advocated for such a fund last year during the protracted debate over approving <u>emergency Zika funding</u>. The blueprint does not specify the source of funds, the amounts to become available, or the HHS official(s) responsible for administering the fund.

The blueprint says there will be reforms of "key public health, emergency preparedness, and prevention programs," many of which are administered by the <u>Centers for Disease Control and Prevention (CDC)</u>, and a restructuring of "similar HHS preparedness grants to reduce overlap and administrative costs." No additional details are provided. It also proposes a new \$500 million CDC block grant for states to address public health challenges, but it does not specify whether these funds would come from CDC's existing budget.

Medical Product Regulation

The Food and Drug Administration (FDA) is funded by a combination of annual appropriations action and user fees, which the agency collects from manufacturers of certain FDA-regulated products. The amount of user fees FDA collects has increased over the past 25 years, both in absolute terms and as a share of its overall budget. User fees now account for 43% of FDA's funding.

The budget blueprint includes a proposal that FDA's medical product user fees be increased in FY2018 to "over \$2 billion" from the current level of about \$1.4 billion, and "replac[e] the need for new budget authority to cover premarket review costs." Congress is gearing up to consider another five-year <u>reauthorization</u> of FDA's medical product user fee programs based on new and, in general, larger fee amounts negotiated by FDA and the drug and medical device industries. Any user fee proposal in the budget that goes beyond the amounts that have already been agreed to may require further negotiation with the industry.

Health Care Services

The budget blueprint supports safety net providers that "deliver critical health care services to low-income and vulnerable populations." It cites as examples of such programs, the <u>federal health centers program</u> and the <u>Ryan White HIV/AIDS program</u>—both of which are administered by the <u>Health Resources and Services Administration (HRSA)</u>— as well as the <u>Indian Health Service</u>. While the blueprint proposes continued funding for these "highest priority" programs, as well as supporting the <u>National Health Service Corps</u>, it proposes a \$403 million cut to HRSA's <u>health professions and nursing education and training programs</u>.

Congress once again is considering extending funding for the ACA's <u>Community Health Center Fund (CHCF)</u>, which gives HRSA additional funds for the health centers program and the NHSC. CHCF <u>funding ends</u> this year under current law.

The blueprint includes a "\$500 million increase above [FY]2016 enacted levels" for opioid abuse prevention and treatment programs administered by the <u>Substance Abuse and Mental Health Services Administration (SAMHSA)</u>. The <u>21st Century Cures Act</u> authorized \$500 million to be appropriated for each of FY2017 and FY2018 for <u>state grants to</u> address the opioid abuse crisis. The <u>second continuing resolution</u>, under which most of the government is currently operating, appropriated \$500 million for FY2017 pursuant to this authority. The blueprint proposal does not indicate

whether it would be additional funding above this level.